UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,586	12/29/2003	Martin R. Willard	1001.1714101	8579

28075 7590 09/24/2007
CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
BRUENJES, CHRISTOPHER P	
ART UNIT	**PAPER NUMBER**
1772	

MAIL DATE	DELIVERY MODE
09/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED
SEP 24 2007
GROUP 1700

Application Number: 10/750,586
Filing Date: December 29, 2003
Appellant(s): WILLARD ET AL.

David M. Crompton
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 10, 2007 appealing from the Office action mailed January 10, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

EP 1 068 876 A2	ITOU et al	1-2001
US 5,258,160	UTSUMI et al	11-1993

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 28-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itou et al (EP 1 068 876 A2) in view of Utsumi et al (USPN 5,258,160).

Regarding claims 28 and 29, Itou et al teach a catheter shaft comprising a proximal portion, a distal portion, and an intermediate portion between the proximal and distal portions (col.3, l.23-27). A first resin layer is arranged in a first region of the tubular member and consists of a first resin material disposed in a dense spiral or mesh and a second resin material disposed in a sparse spiral or mesh, and a second resin layer is arranged in a second region of the tubular member and consists of the second resin material disposed in a dense spiral or mesh and the first resin material disposed in a sparse spiral or mesh. The intermediate region between the first and second regions consists of the first resin material disposed in a spiral or mesh of a disposing density intermediate between the disposing densities in the first and second regions

and the second resin material disposed in a spiral or mesh in a disposing density intermediate between the disposing densities in the first and second regions (col.3, l.27-45). The first region represents the proximal portion and the second region represents the distal portion of the catheter shaft (col.3, l.46-50). The first resin material has a flexural rigidity higher than that of the second resin material (col.4, l.23-25). Therefore, Itou et al teach that the proximal portion is predominantly a more rigid resin and the distal portion is predominantly a less rigid resin. After the spiral shaped material is disposed in the shaft the first and second materials are melted and mixed or fused and then solidified (col.4, l.26-33). Therefore, the layer is a blend of the two materials. Itou et al specifically states that the first and second materials are melted completely and solidified in a uniformly mixed or fused state (col.15, l.29-32). If a material is uniformly mixed then it is homogenously blended. Specifically, with regard to claims 28-29, the proximal portion has a concentration of the more rigid material within the claimed range of 80 to 95% by weight and a concentration of the less rigid material within the claimed range of 5 to 20% (col.10, l.32-37). The distal portion has a concentration of the more rigid material within the claimed range of 5 to 20% and a concentration of the less rigid material within the claimed range of 80 to 95% (col.10, l.38-43). The intermediate portion obviously has a concentration of the more rigid material within the claimed range of 20 and 50% and a concentration of the less rigid material within the claimed range of 50 to 80%, since the concentration of the two materials are values between the values of the concentration of the respective materials in the proximal and distal portions. The materials chosen for the formation of the blend material are a combination of at least two material chosen form a group that includes polyoxymethylene and polyester elastomers (col.9, l.13-30), in which the polyester elastomers is described as a polyether

polyester (col.11, l.46-53). Regarding claims 30 and 39, the catheter shaft further comprises an inner polytetrafluoroethylene tubular member disposed within the polymer blend shaft (col.11, l.19-31 as the base tube or col.12, l.24-33 as the low friction layer). Regarding claims 32 and 40, the catheter shaft further comprises a braided metallic support member disposed between the inner polytetrafluoroethylene tubular member and the polymer blend shaft (col.11, l.57 – col.12, l.11). Regarding claims 37-38 and 42-43, the catheter shaft further comprises a distal tip coupled to the distal portion of the catheter shaft made completely from the less rigid material (col.3, l.19-22). Regarding claim 31, the inner layer comprises polyethylene (col.11, l.19-31 as the base tube or col.12, l.24-33 as the low friction layer). Regarding claim 33, the support member includes a coil (col.12, l.4-6). Regarding claim 36, Itou et al teach that the catheter shaft taught is used in the manufacture of a balloon catheter (col.23, l.21-32) having the limitations of claim 39 shown above, and would necessarily have a balloon coupled to the distal portion of the outer tubular member in order to be considered a balloon catheter. Regarding claim 34, the inner tubular member defines a guidewire lumen extending therethrough (col.12, l.41-47). Regarding claim 35, the balloon catheter obviously contains an inflation lumen between the inner tubular member and outer tubular member because the catheter is a balloon catheter and balloon catheters require an inflation lumen.

Itou et al fail to explicitly teach that polyoxymethylene is chosen as the more rigid material and that the polyether polyester is chosen as the less rigid material. However, Utsumi et al teach that in the art of forming catheters having a varying rigidity longitudinally throughout the catheter, polyester elastomer such as polyether polyester taught by Itou et al is commonly used as a the flexible material, and polyoxymethylene taught by Itou et al is commonly used as a

rigid material. One of ordinary skill in the art would have recognized that Itou et al teach that polyoxymethylene and polyether polyester are materials that are used in the formation of the polymer blend layer of the catheter of Itou et al and that polyoxymethylene is a known torque transmitting material for formation of rigidity varying catheters and that polyether polyester is a known flexible material for formation of rigidity varying catheters, as taught by Utsumi et al.

Therefore, it would have been obvious to select polyoxymethylene as the more rigid material of Itou et al and polyether polyester as the less rigid material of Itou et al, since polyoxymethylene is known in the art as a commonly used rigid material for this particular purpose and polyether polyester is known in the art as a commonly used flexible material for this particular purpose, as taught by Utsumi et al, and it would be obvious to select materials form the group taught in Itou et al to produce the catheter shaft of Itou et al.

Regarding claim 41, Itou et al teach that the proximal portion, intermediate portion, and distal portion define a total shaft length and that the lengths of the individual regions depend on the shape, kind, etc., of the catheter, and are not particularly limited (col.26, l.10-12). Itou et al goes on to teach the lengths of the regions with regard to one particular type of catheter, in which the proximal portion (formed of regions 22 and 23 combined) is 580 to 1150 mm, the intermediate portion (region 24) is 20 to 80mm, and the distal portion (region 25) is 5 to 20mm (col.26, l.12-20). Note the region 26 is the distal tip. It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the lengths of the individual portions within the claimed ranges, since the lengths would be determined based on the size, kind, type, etc., of the catheter and based on the fact that the cited example teaches length ranges that overlap with the claimed ranges.

(10) Response to Argument

Appellant argues Itou and Utsumi fail to teach or suggest all of the claimed limitations. Specifically, Appellant argues Itou and Utsumi fail to teach that the polyoxymethylene and polyether polyester are homogeneously blended.

In response to Appellant's argument that Itou fails to teach homogenously blending of the two materials, Itou teaches that the two materials are melted and fused together to form a uniformly mixed composition. Applicant fails to teach the degree of homogeneity required by the limitation "homogeneously blended", therefore the broadest reasonable interpretation of "homogeneously blended" would include uniformly mixed as taught by Itou.

In response to Appellant's argument that Itou fail to teach any mechanical agitation in uniformly mixing the materials, mechanical agitation is not claimed in the claimed invention and homogeneously blended is not defined in Appellant's specification as requiring mechanical agitation to be achieved. Therefore, when viewing "homogeneously blended" for its broadest reasonable interpretation the uniformly mixed state of Itou would meet the claimed limitation.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Christopher P Bruenjes
Examiner
Art Unit 1772 CPB

CPB
September 17, 2007

Conferees:

Romulo Delmendo

Rena Dye

RENA DYE
SUPERVISORY PATENT EXAMINER
AU 1772

David M. Crompton
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue
Suite 800
Minneapolis, Minnesota 55403-2420